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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,444	12/21/2001	Kang P. Lee	ASPEN 112 US	1737

7590 06/30/2003
Bruce F. Jacobs
P.O. Box 390438
Cambridge, MA 02139

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/30/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,444

Applicant(s)

LEE ET AL.

Examiner

Mina Haghighatian

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 04/28/03 is entered. No new claims are added and no claims are cancelled. Claims 1-16 are pending. However it is noted that the Remarks on line 2 indicate that "independent claims 1 and 13 have been amended". There is no amendment seen on claim 13. Also in the "Clean Version" the amendment of claim 1 does not correspond to the amendment of claim 1 on page 1.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1 and 5-7 under 35 U.S.C. 103(a) as being unpatentable over Unger (6,403,056 B1) is maintained.

The rejection of claims 2-4 and 8-16 under 35 U.S.C. 103(a) as being unpatentable over Unger (6,403,056 B1) as applied to claims 1 and 5-7 above, and further in view of Abbott et al (6,277,489) is maintained.

Response to Arguments

Applicant's arguments filed 04/28/03 have been fully considered but they are not persuasive.

Applicant argues that "Unger does not teach the use of aerogels as drug delivery agents under any set of delivery conditions". This is not persuasive because 1) the entire reference is concerned with "drug delivery" and "targeted drug delivery".

Applicant argues that "Unger goes on to refer to a host of other potential modes of delivery, the most relevant of which is the pulmonary inhalation of "gas filled" vesicles formed by "spray drying". Then on next page (page 4 of remarks) applicant states that "an aerogel is simply not a vesicle and one does not suggest the other. An aerogel is... a solid structure that is filled with a gas (**never a liquid**)". Applicant's arguments are confusing here. If applicant's aerogels are gas filled and Unger's vesicles (aerogels) are gas filled, what is the difference? Also applicant's arguments stating that an aerogel is not a vesicle is not persuasive because the instant claims do not exclude this limitation. Unger is clearly teaching that an aerogel can be a vesicle which is characterized by a plurality of internal voids. Unger also teaches that the internal void of the vesicles may be filled with water, oil, liquids, gases, bioactive agents, etc.

Applicant argues that "Unger does not teach that its vesicle can possibly be obtained by any other drying technique". This is not commensurate with the scope of the claims because instant claims are drawn to a product and not a method of preparing vesicles. The method of making vesicles (aerogels) is not within the scope of the instant claims. Instant claim 1 requires an aerogel with an effective amount of a therapeutically active agent. Unger teaches and meets this limitation.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within


TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghigatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghigatian
June 26, 2003


MICHAEL G. HARTLEY
PRIMARY EXAMINER